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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------------|------------------------|
| 10/810,518 | 03/26/2004 | Thomas H. Barrows | 010414-9012 | 1213 |
| 23510 7590 08/29/2007 MICHAEL BEST & FRIEDRICH LLP ONE SOUTH PINCKNEY STREET P O BOX 1806 MADISON, WI 53701 | | | EXAMINER WARE, DEBORAH K | |
| | | | ART UNIT 1651 | PAPER NUMBER |
| | | | MAIL DATE 08/29/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/810,518

Applicant(s)

BARROWS ET AL.

Examiner

Deborah K. Ware

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-50 is/are pending in the application.
- 4a) Of the above claim(s) 49 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 June 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 32-50 are pending in this Application.

Election/Restrictions

This application contains claims 49-50 drawn to an invention nonelected with traverse in the reply filed on September 19, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 49-50 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group III, there being no allowable generic or linking claim.

Claims 32-48 are reconsidered on the merits.

Amendment Response

The Preliminary Amendment filed August 8, 2004 and May 25, 2006 have been received and entered. Claims 1-31 were canceled.

Drawings

The Drawings filed June 5, 2007, and miscellaneous incoming letter therewith addressing the non-compliance notice regarding the drawings filed on April 13, 2007, which were found to be non-compliant are noted. Furthermore, it is noted on the record that the Figures 4-6 have been resubmitted as black and white photographs and an amendment to the specification has also been submitted for a description of the Figure 6. Hence the objection to the Drawings of record has been withdrawn.

Information Disclosure Statement

The information disclosure statements (IDSs) submitted on May 16, 2005; November 28, 2005; April 10, 2006 and April 25, 2006 were received. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-45 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by US2003/0049839A1 (Romero-Ortega et al), cited on enclosed PTO-892 Form.

Claims are drawn to a graft comprising a bioabsorbable filament having a central lumen and skin cells disposed within the lumen.

Art Unit: 1651

Romero-Ortega et al teach a graft comprising a bioabsorbable filament having a central lumen and skin cells disposed within and adjacent to the lumen, in terms of a cell growth scaffold providing channels comprising extracellular matrix gel (see abstract and page 4, column 1 [0027], lines 4-5. Also note page 5, column 1, [0042], line 3 and column 2, [0053], lines 13-15. The skin includes epidermal cells and dermal cells. The lumen inherently has an interior wall because the skin cells are disposed within the channels comprising the lumen and adhere to the interior surface, note page 4, [0029], lines 1-4. Furthermore, the lumen is inherently smooth, porous, hydrophilic and porous because it is comprised of extracellular matrix gel which has all of these properties. In addition the gel is a well recognized bioabsorbable material which has attachment binding site moieties.

The claims are identical to the teachings of Romero-Ortega et al and are, therefore, considered to be anticipated by the teachings therein. For reasons noted above certain features if not specifically disclosed are considered to be inherent.

Response to Arguments

Applicants' arguments filed April 13, 2007, have been fully considered but they are not persuasive. The argument that each and every element of the claim is not disclosed is noted. However, the language which has been newly added to the claims does not necessarily require the skin cells to initiate hair follicle neogenesis but just that they be capable of initiating hair follicle neogenesis. Furthermore, Romero-Ortega et al specifically teach at page 5, column 2, [0053], line 15, cells for the tissue engineering of

Art Unit: 1651

skin, hence dermal and epidermal cells are intrinsically comprised by these cells as these cells are for the tissue engineering of skin.

The reference does inherently disclose a graft comprising epidermal or dermal cells and while there is no specific teaching of initiating hair follicle neogenesis the disclosed prior art cells are believed by the Examiner to be inherently capable of initiating hair follicle neogenesis because the reference does disclose cells for the growth of skin. Skin contains hair follicles, therefore, the cells would have to be capable of initiating hair follicle neogenesis. However, the newly added language does not require hair follicle neogenesis because the cells only need be capable of the neogenesis.

In response to Applicants' argument that tissue engineered skin is typically devoid of hair follicles, the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, this point of teaching by the instant specification, referred by Applicants at page 10, lines 29-32, also indicates that this is not always the case and is only a typical one and may be dependent upon the conditions employed during tissue engineering processes.

The arguments are not deemed persuasive and the rejection is sustained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1651

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US2003/0049839 ('839), cited above, in view of US2002/0090725 (Simpson et al), cited on enclosed PTO-892 Form.

Claims and '839 are discussed above.

Simpson et al teach that cell attachment binding site moieties, such as Arg-Gly-Asp, known as the RGD site which is a peptide sequence present in many extracellular matrix materials, note page 7, [0079], lines 10-12, which serves as a binding site for cell adhesion.

The claims differ from '839 in that the RGD sequence or peptide comprising a cell attachment domain sequence Arg-Gly-Asp is not specifically disclosed.

It would have been obvious to one of ordinary skill in the art to provide the extracellular matrix gel disclosed by '389 for cell adhesion because it is well known as disclosed by Simpson et al to provide for a cell attachment domain sequence Arg-Gly-

Art Unit: 1651

Asp. Clearly one of skill would have been motivated by the teachings of "389 and Simpson et al to provide for a bioabsorbable material which has cell attachment binding site moieties present to serve as a binding site for skin cell adhesion within the lumen. Thus, the claims are deemed prima facie obvious over the cited prior art.

Response to Arguments

Applicants' arguments filed April 13, 2007, have been fully considered but they are not persuasive. Applicants argue that Simpson et al do not teach the use of cells capable of initiating hair follicle neogenesis, however, as noted above these cells are disclosed by Romero-Ortega et al of which the newly claimed feature of initiating hair follicle neogenesis is inherent to the cells of the primary reference. Thus, Simpson does not have to teach the newly added claim feature because it is applied for its teaching of the RGD sequence or peptide as noted above. The combination of Romero-Ortega et al in view of Simpson et al teach, intrinsically express or at least suggest all of the claimed limitations and features of the newly amended claims. Thus, the rejection is sustained for reasons above and those of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1651

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed. Therefore, the claims are properly rejected.

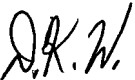
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

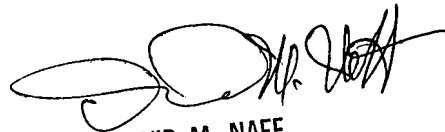
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Deborah K. Ware
August 18, 2007



DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 128/657